DEPARTMENT OF HEALTH AND FAMILY SERVICES
Division of Public Health
DPH 45012 (07/03)

STATE OF WISCONSIN
Bureau of Environmental Health
Radiation Protection Section
(608) 267-4797

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE FOR A COMMERICAL RADIOPHARMACY

The Wisconsin Department of Health and Family Services is requesting disclosure of all information on this application for the purpose of obtaining a radioactive material license. Failure to provide any information may result in denial or delay of a radioactive material license.

Instructions: Complete all items if this is an initial application or an application for renewal of a license. Refer to WISREG " Guidance for Commercial Radiopharmacy." Use supplementary sheets where necessary. Retain one copy and submit original of the entire application to the State of Wisconsin, Department of Health and Family Services, P.O. Box 2659, Madison, WI 53701-2659

APPLICATION TYPE

Item 1 Type Of Application (Check One Box)

☐ New License ☐ Renewal License Number _____ ☐ Amendment License Number _____

CONTACT INFORMATION

Item 2 Name And Mailing Address Of Applicant:	**Item 3 Person To Contact Regarding Application:**
Applicant's Telephone Number (Include Area Code):	**Contact's Telephone Number** (Include Area Code):

LOCATION OF RADIOACTIVE MATERIAL

Item 4 Address(es) Where Radioactive Material Will Be Used Or Possessed (Do not use Post Office Box):

Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)
Address	Telephone Number (Include area code)

RADIATION SAFETY OFFICER

Item 5 Radiation Safety Officer (RSO) (Check all that apply and attach evidence of training and experience)

NAME_____ TELEPHONE NUMBER_____
(Include area code)

☐ We will submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO.

AND EITHER

☐ A copy of the license (DHFS, the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User.

OR

☐ A description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. Appendix G in WISREG 'Guidance for Commercial Radiopharmacy' should be used in documenting and determining required training and experience.

AUTHORIZED NUCLEAR PHARMACIST

Item 6 Authorized Nuclear Pharmacist (ANP) (Check all that apply and attach evidence of training and experience)

NAME_____ TELEPHONE NUMBER _____
(Include area code)

☐ We will provide a copy of the State pharmacy licensure or registration for each pharmacist.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (DHFS, the NRC or an Agreement State) on which the individual was specifically named as an ANP.

OR

☐ We will provide a copy of the permit maintained by a licensee of broad scope.

OR

☐ We will provide a copy of the certification(s) for the radiopharmacy board(s) approved by DHFS.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.

OR

☐ We will provide a written certification, signed by a preceptor ANP, that the above training and experience as specified in s. HFS 157.61(9) has been completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

AUTHORIZED USERS

Item 7 Authorized Users (AU) (Check all that apply)

☐ We will provide the individual's name and identify types, quantities, and proposed uses of licensed material.

AND ONE OF THE FOLLOWING

☐ We will provide a copy of the license (DHFS, the NRC or an Agreement State) on which the individual was specified as an AU for the types and quantities and proposed uses of licensed materials.

OR

☐ We will provide a copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.

OR

☐ We will provide a description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials is attached. Appendix G in WISREG 'Guidance for Commercial Radiopharmacy', may be helpful in describing the training and experience required.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Item 8.1 Occupationally Exposed Workers And Ancillary Personnel (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training. Procedures are attached.

Item 8.2 Personnel Involved In Hazardous Materials Package Preparation And Transport (Check box if applicable)

☐ We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702 AND 49 CFR 172.704, as applicable. Procedures are attached.

RADIOACTIVE MATERIALS

Item 9 Radioactive Material (Attach additional pages if necessary)

Item 9.1 Radioisotope(s)

Item 9.2 Chemical/Physical Form of radioisotopes requested.

Are open containers of potentially volatile materials (Iodine-131) manipulated at this location? ☐ Yes ☐ No

If yes, process and engineering controls must be described.

Are sealed sources used at this location? ☐ Yes ☐ No

If yes, please fill out Items 9.3 – 9.5, otherwise proceed to Item 9.6

Item 9.3 Sealed Source Manufacturer or Distributor and Model Number of sealed sources requested.

Item 9.4 Device Manufacturer or Distributor and Model Number of devices requested.

Item 9.5 Sealed Source Device Registration Sheet Number of sealed sources requested.

Is Depleted Uranium used as a shielding material? ☐ Yes ☐ No

If yes, specify the total amount (in Kilograms) _____

Item 9.6 Maximum possession limit for each radioisotope requested.

Item 9.7 Proposed use for each radioisotope requested.

PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Item 10 Distribution And Redistribution Of Licensed Materials

Item 10.1 Radiopharmaceuticals (Check both boxes)

☐ We will confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to s. HFS 157.13(4)(i), or under equivalent NRC or Agreement State requirements;

AND

☐ We will describe all licensed material to be distributed or redistributed.

Item 10.2 Generators (Check all boxes if using generators)

☐ Confirm that the generators will be obtained from a manufacturer licensed pursuant to s. HFS 157.13(4)(i), or under equivalent NRC or Agreement State requirements.

AND

☐ Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Item 10.3 Redistribution Of Generators (Check all boxes if redistributing generators)

☐ We will submit a description of the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

AND

☐ Confirm that the manufacturer's packaging and labeling will not be altered.

AND

☐ Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

AND

☐ Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

AND

☐ Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

Note: Although redistribution of used generators may be authorized by DHFS, DHFS approval does not relieve the licensee from complying with applicable FDA or other Federal or state requirements.

Item 10.4 Redistribution Of Sealed Sources – For Brachytherapy Or Diagnosis (Check all boxes if redistributing sealed sources, for brachytherapy or diagnosis)

☐ Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued in pursuant to s. HFS 157.13(4)(j), or under equivalent NRC or Agreement State requirements.

AND

☐ Confirm that the manufacturer's packaging, labeling and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.5 Redistribution Of Calibration And Reference Sealed Sources (Check all boxes if redistributing calibration and reference sealed sources)

☐ Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to s. HFS 157.13(4)(j), or under equivalent NRC or Agreement State requirements, to initially distribute such sources.

AND

☐ Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Item 10.6 Redistribution Of Prepackaged Units For In-Vitro Tests (Check box if redistributing prepackaged units for In-vitro tests)

☐ Confirm that the prepackaged units for in-vitro tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for in-vitro tests in accordance with a specific license issued pursuant to s. HFS 157.13(4)(g), or under equivalent license of the NRC or an Agreement State.

Item 10.7 Redistribution To General Licensee (Check all boxes if redistributing to a general licensee)

☐ Confirm that the manufacturer's packaging and labeling of the prepackaged units for in-vitro tests will not be altered in any way.

AND

☐ Confirm that each redistributed prepackaged unit for in-vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

Item 10.8 Redistribution To Specific License (Check both boxes)

☐ Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for in-vitro test will NOT reference general licenses, exempt quantities, or DHFS, NRC, or Agreement State regulations that authorize a general license. (s. HFS 157.11(2)(f))

AND

☐ Confirm that the labeling on redistributed prepackaged units for in-vitro tests will conform to the requirements of s. HFS 157.29(1) and s. HFS 157.29(4).

PREPARATION OF RADIOPHARMACEUTICALS

Item 11 Preparation Of Radiopharmaceuticals (Check box)

☐ We will attach a document that indicates the types of radiopharmaceuticals preparation activities we intend to perform (e.g. compounding of Iodine-131 capsules, radioiodination, and technetium-99m kit preparation). (Document is attached)

SERVICE ACTIVITIES

Item 12 Service Activities (Check box)

☐ We will submit specific procedures for all radiation protection services that we intend to provide to other licensees (e.g. customers). (Procedures are attached)

FACILITIES AND EQUIPMENT

Item 13 Facilities And Equipment (Check boxes and attach diagram.)

☐ We will provide copies of registration or a license from a State Board of Pharmacy as a pharmacy; or evidence that we are operating as a nuclear pharmacy within a state medical institution.

Note: There may be a jurisdiction that does not recognize the practice of commercial radiopharmacy. In these cases, the applicant must submit evidence that it is registered or licensed with the FDA as a drug manufacturer.

AND

☐ We will provide a description of the facilities and equipment to be made available where radioactive material will be used. A diagram should provide be submitted showing the entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to specified scale, or dimensions should be indicated. For additional information refer to WISREG 'Guidance for Commercial Radiopharmacy'. (Description is attached)

RADIATION SAFETY PROGRAM

Item 14 RADIATION SAFETY PROGRAM

Item 14.1 AUDIT PROGRAM

The applicant is not required to, and should not, submit its audit program to DHFS for review during the licensing phase. This matter will be examined during an inspection.

Item 14.2 RADIATION MONITORING INSTRUMENTS (Check one box)

☐ We will use equipment that meets the radiation monitoring instrument specifications and implement the survey meter calibration program published in Appendix J of WISREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J of WISREG 'Guidance for Commercial Radiopharmacy', and instruments will be calibrated by other licensees authorized by DHFS, the NRC or an Agreement State, or a Licensing State to perform that service.

OR

☐ We will provide a description of alternative equipment to be used for radiation monitoring and alternative procedures for the calibration of radiation monitoring equipment. (Procedures are Attached)

Item 14.3 Material Receipt And Accountability (Check all boxes)

☐ We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in s. HFS 157.29(6).

AND

☐ We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

AND

☐ We have developed, and will implement and maintain written procedures for radioactive material accountability and control to ensure that: (Procedures are attached)

1. License possession limits are not exceeded;
2. Radioactive material in storage is secured from unauthorized access or removal;
3. Radioactive material not in storage is maintained under constant surveillance and control; and
4. Records of receipt, transfer, and disposal of licensed material are maintained.

Item 14.4 Occupational Dosimetry (Check all that apply)

☐ We will provide dosimetry processed and evaluated by a NVLAP-approved processor that is exchanged at a frequency recommended by the processor.

AND/OR

☐ We will maintain for inspection by DHFS, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in s. HFS 157.22.

Item 14.5 Public Dose

No response is required, in this license application, however the licensee's evaluation of public dose will be examined during an inspection.

Item 14.6 Safe Use Of Radionuclidies And Emergency Procedures (Check box)

☐ We will develop, implement and maintain safe use of radionuclides and emergency procedures that meets the criteria in the section titled 'Safe Use of Radionuclides and Emergency Procedures' in WISREG 'Guidance for Commercial Radiopharmacy'. (Procedures are Attached)

Item 14.7 Surveys (Check one box)

☐ We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix R of WISREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will develop, implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in s. HFS 157.31; s. HFS 157.25; and s. HFS 157.06.

Item 14.8 Dose Calibrator And Other Dosage Measuring Equipment (Check all that apply)

☐ We will describe the types of systems (measurement or combination of measurement and calculation) that we intend to use for the measurement of alpha-beta, and photon-emitting radioactive drugs.

AND

☐ We will develop, implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in s. HFS 157.13(4)(i). (Procedures are attached)

AND EITHER

☐ We will provide, if applicable, a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers.

OR

☐ We will include, if applicable, a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer, or other entity.

Item 14.9 Radioactive Drug Labeling For Distribution (Check both boxes)

☐ We will describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g. on the "transport radiation shield" or the container used to hold the radioactive drug); (Description is attached)

AND

☐ Agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.

Item 14.10 Radioactive Drug Shielding For Distribution (Check box)

☐ For each drug to be distributed, we will (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

- Indicate the radionuclide and the maximum activity for each type of container (e.g. vial, syringe);
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
- Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

NOTE: It is not acceptable to State that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the "Transport Radiation Shield."

Item 14.11 Leak Test (Check one box)

☐ Leak tests will be performed by an organization authorized by DHFS, the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization licensed by DHFS, the NRC or an Agreement State to provide leak test kits to other licensees according to kit supplier's instructions.

License number of organization authorized to perform or analyze leak test (Specify whether DHFS, NRC, or other Agreement State):

Organization Name: _____ License Number _____

Note: An alternate organization may be used to perform or analyze leak test, without amending the license, provided the organization is specifically authorized by DHFS, NRC or an Agreement State.

OR

☐ We will perform our own leak testing and sample analysis. We will follow the procedures in Appendix L of WISREG 'Guidance for Commercial Radiopharmacy'.

OR

☐ We will submit alternative procedures. (Procedures are attached)

WASTE DISPOSAL AND TRANSFER

Item 15 Waste Disposal And Transfer

Item 15.1 Waste Management (Check box)

☐ We will develop, implement and maintain procedures for waste collection, storage and disposal by any of the authorized methods described in the section titled 'Waste Management' of WISREG 'Guidance for Commercial Radiopharmacy'. We will contact DHFS for guidance to obtain approval of any method(s) of waste disposal other than those discussed in the section titled 'Waste Management of' WISREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

Item 15.2 Returned Waste From Customers (Check one box)

☐ We will develop, implement and maintain procedures for returned waste from customers, that will meet the criteria in the section titled 'Returned Waste from Customers' in WISREG 'Guidance for Commercial Radiopharmacy'. (Procedures are attached)

OR

☐ We will follow the procedures for returned waste from customers in Appendix S of WISREG 'Guidance for Commercial Radiopharmacy'.

SPECIFIC LICENSE FEE

Item 16 License Fees (Refer to Wisconsin Administrative Code HFS 157.10)

Category:	License fee enclosed ☐ Yes ☐ No Amount Enclosed _____

CERTIFICATION (To be signed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 17

I hereby certify that this application was prepared in conformance with Chapter HFS 157 "radiation protection" and that all information contained herein, including any supplements attached hereto, is true and correct to the best of my knowledge and belief.

SIGNATURE - Applicant Or Authorized Individual	Date signed
Print Name and Title of above signatory	